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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,457	03/31/2004	Nicholas R. Benson	DERM1120	1043
28213	7590	09/20/2005	EXAMINER	
DLA PIPER RUDNICK GRAY CARY US, LLP			WHISENANT, ETHAN C	
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SAN DIEGO, CA 92121-2133			1634	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/816,457

Applicant(s)

BENSON, NICHOLAS R.

Examiner

Ethan Whisenant, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-51 and 75-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17, 20-40, 42-50 and 75-81 is/are rejected.
- 7) ☒ Claim(s) 18, 19, 41 and 51 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**NON-FINAL ACTION**

1. The applicant's Preliminary Amendment filed 12 OCT 04 has been entered. Following the entry of the Preliminary Amendment, **Claim(s) 1-51 and 75-81** is/are pending.

**CLAIM OBJECTIONS**

2. **Claim(s) 21** is /are is objected to for the following minor informality.

In **Claim 21** the word "For" is capitalized. This is improper.

**35 USC § 112- 2nd Paragraph**

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH**

4. **Claim(s) 7** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claims 7 and 36 are** indefinite because the phrase "wherein altered expression" lacks proper antecedent basis in Claim 1 and 20.

**Claim 17** is indefinite because the phrase "wherein the taerget area of the skin" lacks proper antecedent basis in Claim 8-9 and 16.

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**35 USC § 102**

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

**CLAIM REJECTIONS UNDER 35 USC § 102**

6. **Claim(s) 1, 3-5** is/are rejected under 35 U.S.C. 102(e) as being anticipated by Rheins et al. [US 6,720,145 (2004)].

Rheins et al. teach a method of detecting expression of genes in the skin which comprises all of the limitations recited in Claims 1 and 3-5.

7. **Claim(s) 1, 3-6, 75-81** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Vogt [WO03/ 001985 (JAN 2003)].

Vogt teach a method of detecting expression of genes in the skin which comprises all of the limitations recited in Claims 1 and 3-6 and 75-81.

**35 USC § 103**

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**CLAIM REJECTIONS UNDER 35 USC § 102/103**

9. **Claim(s) 2** is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vogt [WO03/001985 (JAN 2003)].

Vogt teaches a method of detecting expression of genes in the skin which comprises all of the limitations recited in Claim 2 except these authors do not explicitly teach that the tape they utilized comprises a rubber adhesive on a polyurethane film. Vogt do teach that the tape used maybe, for example, "Duct tape (333 Duct tape, Nashua tape products) or Scotch tape (3M Scotch 810, St. Paul, Minn.). However, a preferred method is to use D-SQUAME (CuDerm, Dallas, Tex.)." As D-SQUAME is a tape which comprises a rubber adhesive on a polyurethane film, it is asserted, absent a showing to the contrary, that the limitation recited in Claim 2 is inherent to Vogt.

10. **Claim(s) 2** is/are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rheins et al. [US 6,720,145 (2004)].

Rheins et al. teach a method of detecting expression of genes in the skin which comprises all of the limitations recited in Claim 2 except these authors do not explicitly teach that the tape they utilized comprises a rubber adhesive on a polyurethane film. Rheins et al. do teach that the tape used maybe, for example, "Duct tape (333 Duct tape, Nashua tape products) or Scotch tape (3M Scotch 810, St. Paul, Minn.). However, a preferred method is to use D-SQUAME (CuDerm, Dallas, Tex.)." As D-SQUAME is a tape which comprises a rubber adhesive on a polyurethane film, it is asserted, absent a showing to the contrary, that the limitation recited in Claim 2 is inherent to Rheins et al.

**CLAIM REJECTIONS UNDER 35 USC § 103**

**11. Claim(s) 6** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Rheins et al. [US 6,720,145 (2004)] as applied to Claim 1 above and further in view of Brown et al. [US 5,807,522 (1998)].

Rheins et al. teach a method of detecting expression of genes in the skin which comprises all of the limitations recited in Claims 6 except these authors do not teach applying the nucleic acids recovered to a microarray. However, as microarrays, as evidenced by Brown et al., were well known prior to the instant invention, as was their use in analyzing gene expression, it would have been, absent an unexpected result *prima facie* obvious to substitute the method of expression analysis utilized by Rheins et al. (i.e. RNase Protection assay) for the microarray expression method described by Brown et al. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

**12. Claim(s) 8-15, 20-35, 37-40, 42-50 and 75-81** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Trepicchio et al. [US 2002/0037538 (2002)] in view of Rheins et al. [US 6,720,145 (2004)].

Trepicchio et al. teach a method of detecting a response of a subject to treatment for a skin disease or pathological skin state which comprises all of the limitations recited in Claims 8 and 20 except these authors do not teach recovering the skin cells used for analysis via the adhesive tape method employed in Claim 8 and 20. However, as evidenced by Rheins et al., the adhesive tape method employed in Claim 8 and 20 was known prior to the instant invention. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan to substitute the adhesive tape method disclosed by Rheins et al. for biopsy method taught in Trepicchio et al. in order to examine gene expression in treated and untreated psoriasis patients. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the

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motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

As regards Claims 11-12, 21-23 see, at least, for example, Tables 1-5.

Trepicchio et al. teach a method for diagnosing psoriasis in a human subject which comprises all of the limitations recited in Claims 42 except these authors do not teach recovering the skin cells used for analysis via the adhesive tape method employed in Claim 42. However, as evidenced by Rheins et al., the adhesive tape method employed in Claim 42 was known prior to the instant invention. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan to substitute the adhesive tape method disclosed by Rheins et al. for the biopsy method taught in Trepicchio et al. in order to examine gene expression and thereby diagnosis psoriasis in human subjects. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

As regards Claims 11-12, 21-23 see, at least, for example, Tables 1-5.

Trepicchio et al. teach a method for identifying a pattern of nucleic acid molecule expression indicative of a disease or pathological condition of a human subject which comprises all of the limitations recited in Claims 75 except these authors do not teach recovering the skin cells used for analysis via the adhesive tape method employed in Claim 75. However, as evidenced by Rheins et al., the adhesive tape method employed in Claim 75 was known prior to the instant invention. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan to substitute the adhesive tape method disclosed by Rheins et al. for the biopsy method taught in Trepicchio et al. in order to examine gene expression in human subjects afflicted with a skin disease. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

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**13. Claim(s) 16-17** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Trepichhhio et al. [US 2002/0037538 (2002)] in view of Rheins et al. [US 6,720,145 (2004)] as applied to Claims 8 and 9 above and further in view of De Simone et al. [US 6,410,019 (2002)].

Trepichhhio et al. in view of Rheins et al. reasonably suggest a method of detecting a response of a subject to treatment for a skin disease or pathological skin state which comprises all of the limitations recited in Claims 16 except these authors do not teach an embodiment wherein the skin condition is dermatitis. However, as evidenced by De Simone et al. alterations in gene expression following the treatment of dermatitis was known prior to the instant invention. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan to modify the method reasonably suggested by the combination of Trepichhhio et al. in view of Rheins et al. wherein instead of psoriasis the disorder is dermatitis as taught by De Simone et al. in order to determine if a particular treatment is useful in the treatment of dermatitis.

#### CLAIM OBJECTIONS

**14. Claim(s) 7, 18-19, 36** is /are is objected to because it is dependent upon a rejected independent base claim, however, Claim 20 would appear to be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

**15. Claim(s) 41, 51** is /are objected to as being dependent upon a rejected base claim, but would appear to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### CONCLUSION

**16. Claim(s) 1-51 and 75-81** is/are rejected and/or objected to for the reason(s) set forth above.



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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (571) 272-0745.

The Central Fax number for the USPTO is (571) 273-8300. Before faxing any papers, please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



**ETHAN WHISENANT  
PRIMARY EXAMINER**

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